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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | | | | | |
|--|--------------|--|---------------------|------------------|----------|---------------|----------|--------------|------|--|
| 09/748,412 | 12/21/2000 | Wouter E. Roorda | 50623.26 | 3752 | | | | | | |
| 7590 04/19/2007 Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111 | | <table border="1"><tr><td>EXAMINER</td></tr><tr><td>GANESAN, SUBA</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">3738</td></tr></table> | | | EXAMINER | GANESAN, SUBA | ART UNIT | PAPER NUMBER | 3738 | |
| EXAMINER | | | | | | | | | | |
| GANESAN, SUBA | | | | | | | | | | |
| ART UNIT | PAPER NUMBER | | | | | | | | | |
| 3738 | | | | | | | | | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | | | | | | | |
| 3 MONTHS | | 04/19/2007 | PAPER | | | | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/748,412 | ROORDA, WOUTER E. | |
| | Examiner Suba Ganesan | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-4, 10, 12, 18-20 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-4, 10, 12, 18-20, 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2-3, 18-19 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (WO 91/12779).
3. Wolff et al. discloses a stent and method of inhibiting restenosis (pg. 1 lines 1-5, fig. 3B) using a polymeric layer (pg. 12 line 15- pg. 15 line 21) with a component for reducing the formation of thrombi (for example heparin, pg. 8 lines 33-37) and a second layer for reducing or preventing infiltration of macrophages into the thrombi (for example aspirin pg. 8 lines 13-23).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Berg et al. (U.S. Pat. No. 5464650).

Wolff et al is explained supra. However, Wolff does not disclose a layer for reducing or preventing infiltration of macrophages into the thrombi comprising betamethasone. Berg teaches the use of betamethasone as a stent coating (eg. Col. 2 lines 30-67). Therefore it would have been obvious to one of ordinary skill in the art to modify the coating of Wolff to include a coating of betamethasone as taught by Berg for the purpose of utilizing the anti-inflammatory properties of betamethasone.

6. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Iguchi et al. (U.S. Pat. No. 5756553).

Wolff is explained supra. However Wolff does not disclose the polymer as ethylene vinyl alcohol. Iguchi et al teaches coatings for stents comprising ethylene vinyl alcohol blended with a drug (e.g. col. 3, lines 29-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of coatings for stents comprising ethylene vinyl alcohol blended with a drug, as taught by Iguchi et al, to the coated stents as per Wolff et al, because ethylene vinyl alcohol has proven to have extremely high stability and safety, and is stably supplied and inexpensive (Iguchi et al col. 3, lines 12-19).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Lee (U.S. Pat. No. 5123917).

Wolff is explained supra. However, Wolff does not disclose a layer made of PTFE. Lee teaches the use of a stent comprising a layer of PTFE impregnated with a

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corticosteroid (col. 4 line 65-col. 5 line 10). Therefore it would have been obvious to one of ordinary skill in the art to combine the PTFE layer impregnated with a corticosteroid, as taught by Lee, with the specific therapeutic agents of Wolff et al for the purpose of creating an inert polymeric layer that delivers a therapeutic agent to minimize tissue proliferation.

Response to Arguments

Applicant's arguments with respect to claims 3,10,18,19,25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 4/10/07



BRIAN E. PELLEGRINO
PRIMARY EXAMINER